



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

**Prospective Grant of Exclusive License: Use of Oligodeoxynucleotide as
Neuroprotectants in Cerebral and Other Ischemic Injury**

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in U.S. provisional patent application No. 60/176/115 (E-078-2000/0-US-01) filed 1/14/2000; PCT application No. PCT/US01/01122 (E-078-2000/0-PCT-02) filed 1/12/2001; U.S. patent No. 7,521,063 (E-078-2000/1-US-01) filed 07/12/2002 and issued 04/21/2009; U.S. patent No. 7,919,477 (E-078-2000/1-US-02) filed 05/10/2007 and issued 04/05/2011; U.S. patent No. 8,232,259 (E-078-2000/1-US-03) filed 02/11/2011 and issued 07/31/2012; E.U. patent No. 1322655 (E-078-2000/0-EP-03) filed 1/12/2001 and issued 11/14/2007 and validated in AT, GB, and IE (E-078-2000/0-AT-05, E-078-2000/0-GB-07, & E-078-2000/0-IE-08) and issued 12/13/2007 as patent No. 6031430 and validated in Germany (E-078-2000/0-DE-06); and E.U. patent

application No. 07021557.9 (E-078-2000/0-EP-04) filed 11/05/2007; each entitled “Oligodeoxynucleotide and Its Use to Induce an Immune Response”; by Klinman et al. (FDA) to Oregon Health Sciences University having a place of business at 3181 S.W. Sam Jackson Park Rd. Portland, Oregon 97239. The patent rights in this invention have been assigned to the United States of America.

DATE: Only written comments and/or application for a license that are received by the NIH Office of Technology Transfer on or before [Insert date 30 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESS: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Tedd Fenn, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Email: fennea@mail.nih.gov; Telephone: 301-435-5031; Facsimile: 301-402-0220.

SUPPLEMENTARY INFORMATION:

The prospective worldwide exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within thirty (30) days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

The subject patents relate to compositions and methods of use of oligodeoxynucleotides (ODNs) expressing CpG motifs to induce immune responses. These ODNs mimic signals of invading pathogens. ODN motifs trigger immune system responses via Toll-like receptor 9 (TLR9). They also mediate inflammatory responses to tissue injury, such as those responses following ischemic damage to the central nervous system. Structural differences between various ODNs may stimulate distinct cell populations, allowing selective targeting of immune responses for therapeutic purposes. Non-human primate and animal models using specific ODNs for pharmacological preconditioning have shown that ODNs may act therapeutically as neuroprotectants from ischemic damage. These TLR ligands as may be useful therapeutically as neuroprotectants in cerebral ischemic injury.

The field of use may be limited to pharmacological preconditioning against excitotoxic injury, ischemia and/or hypoxia.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

May 2, 2013
Date

Richard U. Rodriguez,
Director
Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

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